



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Eckert & Ziegler BEBIG Gmbh  
% Ms. Lu Anne Johnson  
President, Capamed Inc.  
1917 29 3/4 Ave  
RICE LAKE WI 54868

April 17, 2015

Re: K142986

Trade/Device Name: SagiNova

Regulation Number: 21 CFR 892.5700

Regulation Name: Remote controlled radionuclide applicator system

Regulatory Class: II

Product Code: JAQ

Dated: February 16, 2015

Received: February 24, 2015

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". To the left of the signature is a small blue stamp that also contains the letters "FDA".

for

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (*if known*)

K142986

Device Name

SagiNova®

### Indications for Use (*Describe*)

SagiNova® is a family of Eckert & Ziegler BEBIG HDR afterloading systems that are intended to apply brachytherapy treatment to specific body sites (interstitial, intracavitary, intraluminal, and intra-operative or skin surface) with a remote controlled radioactive source. The systems are intended to be used by medical professionals trained in radiation oncology.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



Eckert & Ziegler

Eckert & Ziegler BEBIG GmbH

Robert-Rössle-Str. 10

13125 Berlin

Germany

Phone: (+49)30-941084772

Fax: (+49)30-941084770

Department of Health and Human Services  
Centre of Device and Radiological Health  
Office of Device Evaluation  
Traditional 510(k) section

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**  
**as required by section 21 CFR 807.92**

**Date:** April 2, 2015

**Submitter of 510(k):**

Company name: Eckert & Ziegler BEBIG GmbH

Establishment Registration number: 9617477

Address: Robert Rössle Str. 10  
13125 Berlin  
Germany

Phone: (+49)30941084145

Fax: (+49)30941084112

Correspondent: Heiko Jacobs  
Head of Quality Management and Assurance

**Device Name:**

Trade/Proprietary Name: SagiNova®

Common/Usual Name: High Dose Rate Remote Afterloading Brachytherapy System

**Classification**

Class II

Classification Name: Remote controlled radio-nuclide applicator system

(21 CFR 892.5700 Product Code: JAQ)

**Legally Marketed Devices**

Our devices is based on the legally marketed devices cited in the table below:

Manufacturer	Device	510(k) #
Varian	Gammamed plus IX Brachytherapy Afterloader, Gammamed plus 3/24 IX Brachytherapy Afterloader	K120993
Nucletron	MicroSelectron HDR version 2	K953946

## Reference Device

Scientific methodology was supported by the reference device cited in the table below

Manufacturer	Device	510(k) #
Nucletron	Selectron HDR	K852842

## Device Description:

The SagiNova® HDR afterloading systems are computer controlled medical devices that provide high dose rate brachytherapy treatment by sending a radioactive source into an anatomical site, through an applicator, to deliver a physician prescribed dose.

The SagiNova® HDR afterloading system includes the following models:

Model	Key Features
SagiNova®	Safe shielding suitable for a Co-60 or Ir-192 Source Contains 25 channels
SagiNova® S	Safe shielding suitable for a Co-60 or Ir-192 Source Contains 5 channels
SagiNova® Ir	Safe shielding suitable for a Ir 192 Source Contains 25 channels
SagiNova® Ir-S	Safe shielding suitable for a Ir 192 Source Contains 5 channels

These afterloading systems include the same treatment unit, control unit, applicators, and accessories. They differ in the type of radioactive source that can be accommodated within the shielded safe of the treatment unit and the number of allowed treatment channels.

- The SagiNova® and SagiNova® S are capable of accommodating a Co-60 or Ir-192 radioactive source due to the tungsten and lead safe that is incorporated within the treatment unit. These sources (Co-60 and Ir-192) are nearly identical in construction and clinical performance but differ in half life (Co-60 = 1953.2 days, Ir-192=73.4 days) and maximum activity (Co-60 = 2.2 Ci, Ir-192=13Ci).
- The SagiNova® Ir and SagiNova® Ir-S can only accommodate an Ir-192, 13 Ci radioactive source within the lead safe that is incorporated in the treatment unit.

The number of treatment channels does not interfere with the performance of the device or the size of the implant that can be treated, but strictly limits the number of channels that can be connected at one time. This difference was designed to provide the user with a system that meets their specific clinical requirements. For standard HDR brachytherapy, e.g. GYN treatment, the 5 channel systems (SagiNova® S and SagiNova® Ir-S) are sufficient. While clinics that routinely perform more complex HDR brachytherapy implants, e.g. interstitial treatment, the 25 channel systems (SagiNova®, SagiNova® Ir) are required.

The applicators and accessories are interchangeable between all SagiNova® models and are based on clinically accepted designs required for HDR remote afterloading brachytherapy treatment. The range of applicators includes:

- Intracavitory GYN applicators for the treatment of the vagina, cervix and endometrium including tandem and ovoid, ring applicators and vaginal cylinders.
- Interstitial applicators for the treatment of breast, prostate, and soft tissue including templates, needles and flexible catheters.

- Intraluminal applicators for the treatment of esophagus, lung, nasopharynx including molds, catheters and bougie tubes
- Intraoperative applicators for the treatment of tumor beds include needles, catheters, and molds
- Surface applicators for the treatment of skin surface and mucosa including flexible molds.

The applicators are available for different imaging modalities including CT/MR and X-ray imaging. The applicators are securely connected to the SagiNova® with specially designed transfer tubes or connectors. The transfer tube designs are based on the type of applicator to be connected to the treatment unit, e.g. "Easy Click" transfer tubes for plastic needles and catheters, Transfer Tubes for GYN applicators and metal needles and connectors for universal applicators.

The different components of the SagiNova® HDR remote afterloading system work together to provide safe and effective HDR brachytherapy treatment to physician prescribed treatment areas.

**Intended use:**

SagiNova® is a family of Eckert & Ziegler BEBIG HDR afterloading systems that are intended to provide brachytherapy treatment to specific body sites (interstitial, intracavitary, intraluminal, and intra-operative or skin surface) with a remote controlled radioactive source. The systems are intended to be used by medical professionals trained in radiation oncology.

**Summary of the Technical Characteristics**

SagiNova® HDR Afterloading Systems and the predicate devices have the same technical characteristics for providing high dose rate brachytherapy which includes: a remote controlled computerized treatment unit, radioactive source, applicators and accessories. These components are exclusively used together to provide a prescribed high dose rate brachytherapy treatment. The systems utilize a small, high activity radioactive source which is dispatched from the machine into the treatment site via a closed system of transfer tubes and applicators. The main difference between the SagiNova® HDR Afterloading Systems the predicate devices is the ability of the SagiNova® and SagiNova S® to accommodate a Co-60 or Ir-192 radioactive source. The use of Co-60 for HDR remote afterloading brachytherapy was demonstrated with the reference device, Selectron HDR. The reference device was an accepted method of HDR remote afterloading brachytherapy treatment before the miniaturized Ir-192 HDR source, attached to a flexible wire, was in clinical use. Due to the size of the original Selectron HDR Co-60 source (2.5 mm pellets) this device could not be used for interstitial treatment, however it was in clinical use for intracavitary and intraluminal HDR brachytherapy treatment. The Co-60 radioactive source, for use with the SagiNova and SagiNova S remote afterloading systems, provides a clinically established HDR brachytherapy treatment method with a re-designed source (miniaturized HDR source attached to a flexible wire) comparable to the predicate device.

For substantial equivalence, the predicate device K120993 was used for the SagiNova® system and K953946 was used for the SagiNova® applicators and accessories. SagiNova® HDR Afterloading Systems and the predicate devices are based on established HDR brachytherapy techniques and are identical in design and functionality. These similarities in design and technology are the basis and reason for substantial equivalence of SagiNova® HDR Afterloading Systems to the legally marketed predicate devices.

### **Summary of Non-clinical testing**

Non-clinical testing of SagiNova® HDR Afterloading System was performed in accordance with the Eckert & Ziegler BEBIG quality system and included comprehensive testing of the system hardware and software, radioactive sources, applicators and accessories. The test results confirmed that the product requirements, identified control measures from the risk management process and requirements from the appropriate standards were met.

Testing was performed from defined test cases with clear acceptance criteria both internally and through external test laboratories. Hardware testing included design, usability, and functionality of the systems and sub-systems, as well as requirements defined in the standards; IEC 60601-2-17, IEC 60601-1, IEC 60601-2, IEC 60601-1-6, IEC 60601-8. Software testing of the treatment control unit included design and functionality testing in accordance with the product specifications, risk control measures and usability requirements. The radioactive sources were extensively tested in accordance with ISO 2919 and through prototype testing of the Co-60 source with the SagiNova® and SagiNova® S afterloading system and the Ir-192 source with the SagiNova®, SagiNova® S SagiNova® Ir, and SagiNova® Ir-S. The results of this testing confirmed the source integrity and all weld connections for both sources, including 100,000 source transfers with the Co-60 source in both models and 25,000 source transfers with the Ir 192 source in all models. The applicator design and functionality testing was performed in accordance with the applicator specifications and risk control measures with additional testing performed for; biocompatibility of the applicator materials (ISO 10993-1, ISO 10993-5, ISO 10993-6, ISO 10993-9, ISO 10993-13, ISO 10993-7), MR Testing of the applicators (ASTM 2052-6, F2213-06e1, F2119-07, F2182-11a, ASTM F2503-13) and sterilization testing for EtO (ISO 11135) and steam sterilization (ISO 17665-1) methods.

The successful results of the SagiNova® HDR remote afterloading system non-clinical testing has confirmed that the product meets the defined functional requirements, the applicable recognized standards and clinical expectations. These results were the same if not better than performed for the predicate devices and confirms that the device is safe and effective for clinical use.

### **Summary of Clinical testing**

Clinical testing was not required to demonstrate substantial equivalence.

### **Conclusion**

The SagiNova® HDR Afterloading Systems have passed all defined criteria and are determined to be safe and effective for clinical use. The systems have performed as well or better than the predicate devices and are therefore considered substantially equivalent to the cleared predicate devices.



Heiko Jacobs  
Head of Quality Management and Assurance  
Eckert & Ziegler BEBIG GmbH  
Berlin Germany

HJA
15. April 2015
Date